

BOARD OF PHARMACY

Final Statement of Reasons - Amended

Subject Matter of Proposed Regulations: Sterile Compounding Standards

Sections Affected: Title 16, Sections 1751 et seq.

Hearing Date: April 29, 2003

Updated Information

The proposed text noticed on February 21, 2003 contained a technical error that has been corrected in the Order of Adoption. Specifically, the noticed text contained references to Title 24 of the California Code of Regulations that did not match those actually contained in existing regulations. This technical correction does not alter the effect of the proposed regulation.

Summary of Comments Received During the 45-Day Comment Period (February 21, 2003 to April 7, 2003)

In an email sent on April 1, 2003, Mr. Darrell Chan recommends exempting pharmacies serving patients in a hospital or are monitored by a home-infusion pharmacy from the record keeping requirements in 1751.3. The comment also suggests that the record retrieval standard be “readily retrievable” instead of the “immediately retrievable” in the proposed regulation. In an email dated April 11, 2003, Mr. Mike Koch recommends the same change. In a letter sent on March 24, 2003, Mr. Gary Bremer recommends the same change.

The board agreed with the comment and amended the provisions of Section 1751.3 in the second 15-Day notice.

In letters dated March 4, 2003, William Blair, Cynthia Hazelton and Joe Grasela recommend restricting the added record keeping requirements in Section 1751.3 to patients in long term care facilities or patients monitored by home health care agencies. Mr. Blair states that the records required are unnecessary except in these specific care settings. In an email dated March 14, 2003, Mr. Joe Grasela supports the position of Mr. Blair.

The board responded that the record keeping requirements in 16CCR1707.1 are sufficient to protect the public safety and removed the additional record keeping requirements in subdivision (a) of Section 1751.3 of the proposed draft. Section 1707.1 was adopted after Section 1751.3 and its record keeping requirements make added record keeping unnecessary.

In an email dated March 12, 2003, Mr. Carl Wiggins suggests that the labels on parenteral solutions in a hospital should not be required to include the pharmacy telephone number. Mr. Wiggins states that this requirement serves no purpose and unnecessarily clutters the label

which contains other important information.

The board agreed with the comment and the regulation was amended to reflect this comment in the text released for the first 15-Day notice.

In an email dated March 13, 2003, Mr. John Sang comments that the federal standard referenced in the proposed regulation has been superseded by a standard adopted by the International Standards Organization (ISO). Mr. Sang further comments that if end product testing requirements have been eliminated, then process validation standards should be established to ensure the quality of aseptic technique.

The board agreed with the comment. The board amended the regulation in the first 15-day notice to require process validation as a quality control mechanism for compounded sterile injectable drug products and to require end product sterility testing for batches of sterile injectable drug products compounded from one or more non-sterile products.

In an email dated February 23, 2003, Mr. Ernest Aldama comments that the definition of “barrier isolator” is unclear.

The board responded that barrier isolator is accepted terminology in the professional literature as is indicated by its use in recognized national guidelines for sterile compounding.

Mr. Aldama further comments that the federal cleanliness standard referenced in the regulation has been superseded by a standard adopted by ISO.

The board agreed with the comment and amended the regulation to require compliance with the relevant standard as approved by the United States General Services Administration.

Mr. Aldama further comments that pharmacy standards published in Title 24 of the California Code of Regulations (CCR) should be published elsewhere in the CCR because Title 24 is not readily available.

The board responded that the provisions published in Title 24 are required to be included in that title and the board does not have discretion to relocate those provisions to Title 16.

Mr. Aldama further comments that section 1751.01 (b) is unclear who will make the required determination when the compounding environment fails to meet pharmacy standards and that most pharmacy personnel do not understand how the environmental control equipment operates.

The board responded that existing law (Business and Professions Code 4115 (c)) regarding the exercise of professional judgment is entirely clear. Other pharmacy personnel are precluded from performing acts requiring professional judgment. Determinations regarding the safety of a compounding environment clearly rely on the professional skill and judgment of a pharmacist.

Mr. Aldama further comments that it is unclear what will satisfy the policies and procedures required by 1751.02.

The board responded that the requirement for policies and procedures clearly enumerates the subjects that must be addressed. The specific nature of the policies and procedures must reflect operations in each individual pharmacy and good professional practice based on the particular types of products compounded in each individual pharmacy. Determinations regarding the adequacy of these policies and procedures are necessarily made on a case by case basis given the factual situation of each applicant pharmacy.

In a letter delivered to the board on March 4, 2003, Mr. Michael Pastrick comments that sterility testing of compounded sterile injectable drug products is not supported by current professional guidelines and that it is only appropriate to perform such testing on large batches of sterile injectable drug products compounded from non-sterile ingredients.

The board responded that the proposed regulation was amended to require process validation as a quality control mechanism for compounded sterile injectable drug products and requires end product sterility testing for batches of sterile injectable drug products compounded from one or more non-sterile products.

Mr. Pastrick further comments that microbial testing of compounded sterile injectable drug products should be mandated whenever there is reason to suspect that the compounded drug product has been contaminated.

The board responded that the proposed regulation was amended to require process validation as a primary form of quality control. The board believes that the systematic evaluation of safe compounding processes required by process validation better protects the public safety than the testing requirement suggested by Mr. Pastrick.

Summary of Comments Received During the Regulation Hearing on April 29, 2003.

In testimony, Mr. William Blair, Ms. Teresa Miller, Mr. John Cronin, Mr. Michael Koch commented that the record keeping requirements were unduly burdensome and would interfere in patient care.

The board agreed with the comment that other existing regulations did provide for adequate recordkeeping and the regulation was amended to delete the additional recordkeeping requirements.

Mr. Michael Pastrick commented that end-product testing was not appropriate as a quality control mechanism and that the board should replace it with process validation.

The board agreed that process validation was at least equally protective of patient safety and amended the regulation to replace end product sterility testing with process validation.

Summary of Comments Received During the First 15-Day Comment Period (June 3, 2003 to June

19, 2003)

In an email dated June 6, 2003, Mr. William Blair commented that he believed the board voted to repeal Section 1751.3 at the April 29, 2003 regulation hearing. In an email dated June 9, 2003, Mr. Mike Koch made the same comment.

The board responded that the comments are appropriate and the comments are reflected in the proposed regulation text released in the second 15-Day notice.

In a letter dated June 18, 2003, Mr. Michael Pastrick commented that the portion of the proposed regulation relating to process validation should be modified to reflect current professional standards.

The board responded that the comments are appropriate and the comments are reflected in the proposed regulation text released in the second 15-Day notice.

Summary of Comments Received During the Second 15-Day Comment Period (July 30, 2003 to August 15, 2003)

In an email dated August 13, 2003, Mr. Michael Pastrick commented that the second 15-Day text required minor technical changes.

The board responded that the changes were appropriate and corresponding technical changes have been made.

Local Mandate:

None.

Business Impact:

The board has determined that the proposed regulatory action could have a significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. However, no equally effective alternatives were identified by the board or by interested parties.

Consideration of Alternatives:

The board has determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.